



**U.S. Department of Justice**

***Carmen M. Ortiz***  
*United States Attorney*  
*District of Massachusetts*

Main Reception: (617) 748-3100

*John Joseph Moakley United States Courthouse*  
*1 Courthouse Way*  
*Suite 9200*  
*Boston, Massachusetts 02210*

October 21, 2010

Geoffrey E. Hobart  
Matthew J. O'Connor  
Covington & Burling LLP  
1201 Pennsylvania Avenue, NW  
Washington, DC 20004-2401

Re: United States v. GlaxoSmithKline LLC

Dear Counsel:

This letter ("Side Letter Agreement") will confirm that, in exchange for full performance of the Plea Agreement entered into by and among the United States of America, acting through the United States Attorney for the District of Massachusetts ("U.S. Attorney") and the Department of Justice (collectively referred to as "the United States") and your client, SB Pharmco Puerto Rico, Inc. ("SB Pharmco"), a copy of which plea agreement is attached hereto as Exhibit One, and in exchange for certain other promises made herein between and among the United States and your client, GlaxoSmithKline LLC (GlaxoSmithKline LLC, its parent, GlaxoSmithKline plc, their direct and indirect subsidiaries and their successors will be referred to as "GlaxoSmithKline"), the United States and GlaxoSmithKline hereby agree as follows:

1. No Criminal Prosecution of GlaxoSmithKline

The United States hereby declines prosecution of GlaxoSmithKline LLC, GlaxoSmithKline plc or any of their direct or indirect subsidiaries (other than SB Pharmco as set forth in the Information) for conduct by or attributable to GlaxoSmithKline or any of its subsidiaries that:

- (a) falls within the scope of the Information to which SB Pharmco is pleading guilty; or



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(b) was either the subject of the grand jury investigation in the District of Massachusetts, or was known to the United States Attorney's Office for the District of Massachusetts or the Office of Consumer Litigation of the Department of Justice prior to the date of this agreement, relating to:

- (i) the production, manufacturing, processing, packing, and/or holding of drugs at SB Pharmco's Cidra, Puerto Rico manufacturing facility between the years 2001 and 2005; or
- (ii) conduct, communications and reporting regarding the Food and Drug Administration's oversight, regulatory inspections and actions regarding the Cidra, Puerto Rico manufacturing facility between the years 2001 and 2005.

The United States does not decline criminal prosecution of GlaxoSmithKline or any of GlaxoSmithKline's related entities for any other conduct beyond that set forth above. Without limitation, for the drugs manufactured at Cidra, this release expressly does not extend to any conduct relating to post-marketing studies or analyses; marketing or promotion; or conduct, communications and/or reporting to the FDA or physicians or customers regarding the safety, efficacy, and/or recommended uses of the drugs concerning issues other than manufacturing, processing, packing and/or holding of the drugs at Cidra.

This Side Letter Agreement is not intended to and does not affect the criminal liability of any individual.

It is understood among the parties to this Side Letter Agreement that the United States' promise not to prosecute GlaxoSmithKline is dependent upon and subject to SB Pharmco fulfilling its material obligations in the Plea Agreement and GlaxoSmithKline fulfilling its material obligations both herein and in the related Civil Settlement Agreement attached hereto as Exhibit Two. If SB Pharmco does not fulfill its material obligations in the Plea Agreement and/or GlaxoSmithKline does not fulfill its material obligations both herein and in the related Civil Settlement Agreement, GlaxoSmithKline agrees to waive any defenses regarding pre-indictment delay, statute of limitations, or Speedy Trial Act with respect to any and all criminal charges that could have been timely brought or pursued as of the date of this letter, as set forth above.

## 2. Cooperation of GlaxoSmithKline

GlaxoSmithKline shall cooperate completely and truthfully in any trial or other proceeding arising out of any ongoing civil, criminal or administrative investigation of its current and former officers, agents, and employees and customers in connection with matters described



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in Paragraph One. GlaxoSmithKline shall make reasonable efforts to facilitate access to, and to encourage the cooperation of, its current and former officers, agents, and employees for interviews sought by law enforcement agents, upon request and reasonable notice in connection with the matters described in Paragraph One. GlaxoSmithKline shall also take reasonable measures to encourage its current and former officers, agents, and employees to testify truthfully and completely before any grand jury, and at any trial or other hearing, at which they are requested to do so by any government entity in connection with matters described in Paragraph One.

In addition, GlaxoSmithKline shall, in connection with matters described in Paragraph One, promptly furnish to law enforcement agents, upon request, all documents and records in its possession, custody or control relating to the conduct that are within the scope of any ongoing federal investigation, trial or other criminal proceeding, and that are not covered by the attorney-client privilege or work product doctrine.

Provided, however, notwithstanding any provision of this Agreement, that: (1) GlaxoSmithKline is not required to request of its current or former officers, agents, or employees that they forego seeking the advice of an attorney or that they act contrary to that advice; (2) GlaxoSmithKline is not required to take any action against its officers, agents, or employees for following their attorney's advice; and (3) GlaxoSmithKline is not required to waive any privilege or claim of work product protection except to the extent set forth in the succeeding paragraph.

GlaxoSmithKline acknowledges that SB Pharmco expressly and unequivocally admits that it knowingly, intentionally and willfully committed the crime charged in the Information and is in fact guilty of that offense. GlaxoSmithKline agrees that it will not make statements inconsistent with this explicit admission of guilt by SB Pharmco to the crime charged in the Information.

### 3. Who Is Bound By Agreement

This letter agreement is binding upon the Attorney General of the United States, the United States Department of Justice, including all United States Attorneys, except that this agreement does not bind the Tax Division of the United States Department of Justice or the Internal Revenue Service of the United States Department of the Treasury. This letter agreement is binding on the Criminal Division of the United States Department of Justice, with the exception of any investigations of GlaxoSmithKline that are or may be conducted in the future by the Fraud Section of the Criminal Division regarding possible violations of the Foreign Corrupt Practices Act and related offenses in connection with the sales and marketing of GlaxoSmithKline's products to foreign customers. A copy of the letter to United States Attorney Carmen M. Ortiz on behalf of the Assistant Attorney General, Criminal Division, Department of Justice, authorizing this Side Letter Agreement is attached as Exhibit Three.

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It is expressly understood that this Side Letter Agreement will have no effect on state or local prosecuting authorities, except as set forth in the civil settlement agreements between GlaxoSmithKline and the various states.

4. Complete Agreement

This Side Letter Agreement, the Plea Agreement with SB Pharmco, the Civil Settlement Agreement, and the Tolling Agreement between GlaxoSmithKline and the United States Attorney dated May 3, 2010, are the complete and only agreements between the parties. No promises, agreements or conditions have been entered into other than those set forth or referred to in the above-identified documents. This agreement supersedes prior understandings, if any, of the parties, whether written or oral. This agreement cannot be modified other than in a written memorandum signed by the parties or on the record in court.

If this letter accurately reflects the agreement entered into between the United States and GlaxoSmithKline LLC and if you are authorized to enter into this agreement on behalf of GlaxoSmithKline LLC, please sign below and return the original of this letter to Assistant U.S. Attorney Susan G. Winkler.

Very truly yours,



CARMEN M. ORTIZ  
United States Attorney  
District of Massachusetts



Susan G. Winkler



Shannon T. Kelley  
Assistant U.S. Attorneys  
District of Massachusetts

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TONY WEST  
ASSISTANT ATTORNEY GENERAL  
CIVIL DIVISION  
U.S. DEPARTMENT OF JUSTICE

By: 

Mark L. Josephs  
Trial Attorney  
Office of Consumer Litigation  
U.S. Department of Justice



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**ACKNOWLEDGMENT OF AGREEMENT**

I am authorized to execute this Side Letter Agreement and the Civil Settlement Agreement on behalf of GlaxoSmithKline LLC. GlaxoSmithKline LLC has been advised of the contents of this Side Letter Agreement, the Civil Settlement Agreement, the Plea Agreement with SB Pharmco, Inc., and the criminal Information charging SB Pharmco, Inc., and has discussed them fully with its counsel. I am further authorized to acknowledge on behalf of GlaxoSmithKline LLC, that these documents fully set forth the agreements made between GlaxoSmithKline, and the United States, and that no additional promises or representations have been made to GlaxoSmithKline, by any officials of the United States Department of Justice in connection with the disposition of this matter, other than those set forth in those documents.

Dated: \_\_\_\_\_

\_\_\_\_\_  
Elpidio Villarreal  
Senior Vice President, Global Litigation  
GlaxoSmithKline LLC

Dated: \_\_\_\_\_

\_\_\_\_\_  
Geoffrey E. Hobart, Esq.  
Matthew J. O'Connor, Esq.  
Covington & Burling LLP  
Counsel for Defendant



**U.S. Department of Justice**

***Carmen M. Ortiz***  
*United States Attorney*  
*District of Massachusetts*

*Main Reception: (617) 748-3100*

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*Suite 9200*  
*Boston, Massachusetts 02210*

October 21, 2010

Geoffrey E. Hobart  
Matthew J. O'Connor  
Covington & Burling LLP  
1201 Pennsylvania Avenue, NW  
Washington, DC 20004-2401

Re: United States v. SB Pharmco Puerto Rico, Inc.

Dear Counsel:

This letter sets forth the Agreement between the United States Attorney for the District of Massachusetts ("the U.S. Attorney") and the United States Department of Justice (collectively, the "United States") and your client, SB Pharmco Puerto Rico, Inc. (hereinafter "SB Pharmco"), in the above-referenced case. The Agreement is as follows:

1. Change of Plea

At the earliest practicable date SB Pharmco shall waive indictment and plead guilty to the one-count Information attached hereto as Exhibit A. Count One of the Information charges that from in or about March 2003 to October 2004, SB Pharmco introduced for delivery into interstate commerce various quantities of adulterated drugs Paxil CR, Avandamet, Kytril, and Bactroban in violation of 21 U.S.C. §§ 331(a), 333(a)(2) and 351(a)(2)(B). SB Pharmco expressly and unequivocally admits that it committed these offenses and further admits that it acted with the intent to defraud or mislead. Defendant expressly and unequivocally further admits that it is in fact guilty of this offense, and agrees that it will not make any statements inconsistent with this explicit admission. SB Pharmco agrees to waive venue, to waive any applicable statutes of limitations, and to waive any legal or procedural defects in the Information.

2. Penalties

SB Pharmco faces the following maximum penalties on Count One of the Information:

- a. A fine of \$500,000, or twice the gross gain derived from the offense or twice the gross loss to a person other than the defendant, whichever is greatest. *See* 18 U.S.C. §§ 3571(c)(5) and (d). Given SB Pharmco's gross gain from its sales of Paxil CR, Avandamet, Kytril and Bactroban that were deemed adulterated between March 2003 and October 2004 totaled \$98,834,224, the maximum possible fine in connection with this count is \$197,668,448.
- b. A term of probation of not more than five (5) years. *See* 18 U.S.C. § 3561(c)(2);
- c. Restitution to any victims of the offense. *See* 18 U.S.C. §§ 3556 and 3663; and
- d. A mandatory special assessment of \$400. *See* 18 U.S.C. § 3013..

3. Sentencing Guidelines

The parties agree that the fine provisions of the United States Sentencing Guidelines ("U.S.S.G.") applicable to organizational defendants for felony violations of the Food, Drug, and Cosmetic Act, *see* U.S.S.G. § 8C2.1, are calculated as follows, and that this calculation takes into account SB Pharmco's conduct under 18 U.S.C. §§ 3553 and 3572:

- a. The parties agree that the base fine is \$98,834,224, which is the pecuniary gain to the organization from the offense. *See* U.S.S.G. §§ 8C2.4(a), 8C2.3.
- b. Pursuant to U.S.S.G. § 8C2.5, the culpability score is six (6), which is determined as follows:
  - i. Base culpability score is five (5) pursuant to U.S.S.G. § 8C2.5(a);
  - ii. Add three (3) points pursuant to U.S.S.G. § 8C2.5(b)(2) in that the organization had 200 or more employees and an individual within high-level personnel of organization participated in, condoned, or was willfully ignorant of the offense; and
  - iii. Deduct two (2) points pursuant to U.S.S.G. § 8C2.5(g)(2) in recognition of SB Pharmco's full cooperation and clearly



demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct.

- iv. Pursuant to U.S.S.G. § 8C2.6, the appropriate multiplier range associated with a culpability score of six (6) is 1.20 to 2.40.
- v. Thus, the advisory Guideline Fine Range is \$118,601,069 to \$197,668,448. *See* U.S.S.G. §§ 8C2.7(a), (b); 18 U.S.C. §§ 3571(c), (d).

4. Agreed Disposition

The United States and SB Pharmco agree pursuant to Fed. R. Crim. P. 11(c)(1)(C) that the appropriate disposition of this case is as follows, and will result in imposition of a reasonable sentence that is sufficient, but not greater than necessary, taking into consideration of all of the factors set forth in 18 U.S.C. §§ 3553(a) and 3572:

- a. A criminal fine of \$140,000,000 - to be paid within one week of the date of sentencing.
- b. Mandatory special assessments totaling \$400 pursuant to 18 U.S.C. § 3013, to be imposed as follows:
- c. Criminal Forfeiture in the amount of \$10,000,000.
- d. In light of the pending civil action, United States of America ex rel. Cheryl Eckard v. GlaxoSmithKline, et al., Civil Action No. 04-10375 (D. Mass.), and the Civil Settlement Agreement between SmithKline Beecham Corporation d/b/a/ GlaxoSmithKline and the United States (which is being signed contemporaneously with this Plea Agreement, and is attached hereto as Exhibit B) which requires the payment of \$600,000,000, plus interest, the parties agree that the complication and prolongation of the sentencing process that would result from an attempt to fashion a proper restitution order outweighs the need to provide restitution to any non-federal victims in this case given that numerous unknown individuals and insurance companies purchased or reimbursed for the drug products in question, and that tracing reimbursements to the various unknown insurance companies and patients and determining the apportionment of payment pertaining to the products at issue would be extraordinarily difficult, if not impossible. *See* 18 U.S.C. § 3663(a)(1)(B)(ii). Accordingly, the United States agrees that it will not seek a separate restitution order as to SB Pharmco as part of the resolution of the Information and the Parties agree that the appropriate disposition of this case does not include a restitution order.

The United States may, at its sole option, be released from its commitments under this Agreement, including, but not limited to, its agreement that this paragraph constitutes the appropriate disposition of this case, if at any time between Defendant's execution of this Agreement and sentencing, SB Pharmco:

- a. Fails to admit a complete factual basis for the plea;
- b. Fails to truthfully admit its conduct in the offenses of conviction;
- c. Falsely denies, or frivolously contests, relevant conduct for which SB Pharmco is accountable under U.S.S.G. § 1B1.3;
- d. Gives false or misleading testimony in any proceeding relating to the criminal conduct charged in this case and any relevant conduct for which SB Pharmco is accountable under U.S.S.G. § 1B1.3;
- e. Engages in acts which form a basis for finding that SB Pharmco has obstructed or impeded the administration of justice under U.S.S.G. § 3C1.1;
- f. Commits a crime; or
- g. Attempts to withdraw its guilty plea.

SB Pharmco expressly understands that it may not withdraw its plea of guilty unless the Court rejects this Agreement under Fed. R. Crim. P. 11(c)(5).

5. No Further Prosecution of SB Pharmco

Pursuant to Fed. R. Crim. P. 11(c)(1)(A), the United States agrees that, other than the charges in the attached Information, it shall not further prosecute SB Pharmco for any additional federal criminal charges or charges under the Food Drug and Cosmetic Act against Defendant with respect to the conduct that:

- (a) falls within the scope of the Information to which SB Pharmco is pleading guilty, or
- (b) was either the subject of the grand jury investigation in the District of Massachusetts or was known to the United States Attorney's Office for the District of Massachusetts or the Office of Consumer Litigation of the Department of Justice prior to the date of this Agreement relating to:



- (i) the production, manufacturing, processing, packing and/or holding of drugs at SB Pharmco's Cidra, Puerto Rico manufacturing facility between the years 2001 and 2005; or
- (ii) conduct, communications and reporting regarding the Food and Drug Administration's oversight, regulatory inspections and actions regarding the Cidra, Puerto Rico manufacturing facility between the years 2001 and 2005.

The United States does not decline criminal prosecution of SB Pharmco for any other conduct beyond that set forth above. Without limitation, for the drugs manufactured at Cidra, this release expressly does not extend to any conduct relating to post-marketing studies or analyses; marketing or promotion; or conduct, communications and/or reporting to the FDA or physicians or customers regarding the safety, efficacy, and/or recommended uses of the drugs concerning issues other than manufacturing, processing, packing and/or holding of the drugs at Cidra.

This declination is expressly contingent upon:

- a. the guilty plea of SB Pharmco to the Information attached hereto as Exhibit A being accepted by the Court and not withdrawn or otherwise challenged; and
- b. SB Pharmco's performance of all of its obligations as set forth in this Agreement and the attached Civil Settlement Agreement.

If SB Pharmco's guilty plea is not accepted by the Court or is withdrawn for any reason, or if SB Pharmco should fail to perform any obligation under this Agreement or the Civil Settlement Agreement, this declination of prosecution shall be null and void.

The United States expressly reserves the right to prosecute any individual, including but not limited to present and former officers, directors, employees, and agents of SB Pharmco, in connection with the conduct encompassed by this plea agreement, within the scope of the grand jury investigation, or known to the United States.

6. Payment of Mandatory Special Assessment

SB Pharmco shall pay the mandatory special assessment to the Clerk of the Court on or before the date of sentencing.

7. Waiver of Right to Appeal and to Bring Other Challenge

- a. SB Pharmco has conferred with its attorney and understands that it has the right to challenge its convictions in the United States Court of Appeals for the First Circuit ("direct appeal"). SB Pharmco also understands that it

may, in some circumstances, be able to challenge its convictions in a future proceeding (such as, for example, in a collateral challenge pursuant to 28 U.S.C. § 2255 or 28 U.S.C. § 2241). SB Pharmco waives any right it has to challenge its conviction on direct appeal or in any future proceeding.

- b. SB Pharmco has conferred with its attorney and understands that defendants ordinarily have a right to appeal their sentences and may sometimes challenge their sentences in future proceedings. SB Pharmco understands, however, that once the Court accepts this Rule 11(c)(1)(C) plea agreement, the Court is bound by the parties' agreed-upon sentence. SB Pharmco may not contest the agreed-upon sentence in an appeal or challenge the sentence in a future proceeding in federal court. Similarly, the Court has no authority to modify an agreed-upon sentence under 18 U.S.C. § 3582(c), even if the Sentencing Guidelines are later modified in a way that appears favorable to Defendant. Given that a defendant who agrees to a specific sentence cannot later challenge it, and also because SB Pharmco desires to obtain the benefits of this Agreement, SB Pharmco agrees that it will not challenge the sentence imposed in an appeal or other future proceeding. SB Pharmco also agrees that it will not seek to challenge the sentence in an appeal or future proceeding even if the Court rejects one or more positions advocated by any party at sentencing.
- c. The United States agrees that it will not appeal the imposition by the Court of the sentence agreed to by the parties as set out in Paragraph 4, even if the Court rejects one or more positions advocated by a party at sentencing.

#### 8. Cooperation

SB Pharmco shall cooperate completely and truthfully in any trial or other proceeding arising out of any ongoing civil, criminal or administrative investigation of its current and former officers, agents, employees, and customers in connection with the matters described in the Information. SB Pharmco shall make reasonable efforts to facilitate access to, and to encourage the cooperation of, its current and former officers, agents, and employees for interviews sought by law enforcement agents, upon request and reasonable notice in connection with matters described in the Information. SB Pharmco shall also take reasonable measures to encourage its current and former officers, agents, and employees to testify truthfully and completely before any grand jury, and at any trial or other hearing, at which they are requested to do so by any government entity in connection with matters described in the Information.

In addition, SB Pharmco shall furnish to law enforcement agents, upon request, all documents and records in its possession, custody or control relating to the conduct that is within the scope of any ongoing federal investigation, trial or other criminal proceeding in connection with matters described in the Information, and that are not covered by the attorney-client



privilege or work product doctrine.

Provided, however, notwithstanding any provision of this Agreement, that: (1) SB Pharmco is not required to request of its current or former officers, agents, or employees that they forego seeking the advice of an attorney nor that they act contrary to that advice; (2) SB Pharmco is not required to take any action against its officers, agents, or employees for following their attorney's advice; and (3) SB Pharmco is not required to waive any privilege or claim of work product protection.

9. Probation Department Not Bound By Agreement

The sentencing disposition agreed upon by the parties and their respective calculations under the Sentencing Guidelines are not binding upon the United States Probation Office.

10. Forfeiture

SB Pharmco will forfeit to the United States assets subject to forfeiture pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461(c) as a result of its guilty plea.

SB Pharmco admits that the value of the quantities of Paxil CR and Avandamet that were adulterated and distributed in violation of 21 U.S.C. § 331, totaled at least \$10,000,000 in United States currency. SB Pharmco acknowledges and agrees that the quantities of Paxil CR and Avandamet which were adulterated and distributed in violation of 21 U.S.C. § 331 cannot be located upon exercise of due diligence, or have been transferred or sold to, or deposited with, a third party, placed beyond the jurisdiction of the Court, substantially diminished in value, or commingled with other property which cannot be divided without difficulty. Accordingly, SB Pharmco agrees that the United States is entitled to forfeit as "substitute assets" any other assets of SB Pharmco up to the value of the now missing directly forfeitable assets.

SB Pharmco agrees that, no later than one week after sentencing, it shall remit the amount of \$10,000,000 in United States currency to the United States Marshals Service pursuant to wire instructions provided by the United States Attorney's Office. SB Pharmco and the United States agree that this payment shall satisfy any and all forfeiture obligations that SB Pharmco may have as a result of its guilty plea.

Forfeiture of substitute assets shall not be deemed an alteration of SB Pharmco's sentence. The forfeitures set forth herein shall not satisfy or offset any fine, restitution, cost of imprisonment, or other penalty imposed upon SB Pharmco, nor shall the forfeiture be used to offset SB Pharmco's tax liability or any other debt owed to the United States.

SB Pharmco agrees to consent to the entry of orders of forfeiture for the \$10,000,000 in United States currency, and waives the requirements of Federal Rules of Criminal Procedure 32.2 and 43(a) regarding the notice of the forfeiture in the charging instrument, entry of a preliminary order of forfeiture, announcement of the forfeiture at sentencing, and incorporation of the

forfeiture in the judgment. SB Pharmco acknowledges that it understands that the forfeiture of assets is part of the sentence that may be imposed in this case and waives any failure by the court to advise it of this, pursuant to Rule 11(b)(1)(J), at the time the guilty plea is accepted.

In addition to all other waivers or releases set forth in this Agreement, SB Pharmco hereby waives any and all claims arising from or relating to the forfeitures set forth in this section, including, without limitation, any claims arising under the Double Jeopardy Clause of the Fifth Amendment, or the Excessive Fines Clause of the Eighth Amendment, to the United States Constitution, or any other provision of state or federal law.

The United States District Court for the District of Massachusetts shall retain jurisdiction to enforce the provisions of this section.

11. Fed. R. Crim. P. 11(c)(1)(C) Agreement

SB Pharmco's plea will be tendered pursuant to Fed. R. Crim. P. 11(c)(1)(C). SB Pharmco cannot withdraw its plea of guilty unless the sentencing judge rejects this Agreement or fails to impose a sentence consistent herewith. If the sentencing judge rejects this Agreement or fails to impose a sentence consistent herewith, this Agreement shall be null and void at the option of either the United States or SB Pharmco, with the exception of paragraph 13 (Waiver of Defenses) which shall remain in full effect.

SB Pharmco may seek sentencing by the District Court immediately following the Rule 11 plea hearing. The United States does not object to the Court proceeding to sentence SB Pharmco immediately following the Rule 11 plea hearing or in the absence of a Presentence Report in this case. SB Pharmco understands that the decision whether to proceed immediately following the plea hearing with the sentencing proceeding, and to do so without a Presentence Report, is exclusively that of the United States District Court.

12. Civil and Administrative Liability

By entering into this Agreement, the Government does not compromise any civil or administrative liability, including but not limited to any False Claims Act or tax liability, which SB Pharmco may have incurred or may incur as a result of its conduct and its plea of guilty to the attached Information.

SB Pharmco's civil liability to the United States in connection with certain of the matters under investigation by the Government is resolved in the Civil Settlement Agreement with GlaxoSmithKline LLC, attached as Exhibit B, according to the terms set forth in that Agreement.



### 13. Waiver of Defenses

If SB Pharmco's guilty plea is not accepted by the Court for whatever reason, if SB Pharmco's guilty plea is later withdrawn or otherwise successfully challenged by SB Pharmco for whatever reason, or if SB Pharmco breaches this Agreement, SB Pharmco hereby waives, and agrees it will not interpose, any defense to any charges brought against it which it might otherwise have under the Constitution for pre-indictment delay, any statute of limitations, or the Speedy Trial Act, except any such defense that SB Pharmco may already have for conduct occurring before August 27, 2002, as further described in the parties' tolling agreement dated May 3, 2010, attached hereto as Exhibit C. This waiver is effective provided that charges are filed within six months of the date on which such guilty plea is rejected, withdrawn, or successfully challenged, or a breach is declared by the United States.

### 14. Breach of Agreement

If the United States determines that SB Pharmco has failed to comply with any provision of this Agreement, or has committed any crime following its execution of this Agreement, the United States may, at its sole option, be released from its commitments under this Agreement in its entirety by notifying SB Pharmco, through counsel or otherwise, in writing. The United States may also pursue all remedies available under the law, even if it elects not to be released from its commitments under this Agreement. SB Pharmco recognizes that no such breach by it of an obligation under this Agreement shall give rise to grounds for withdrawal of its guilty plea. SB Pharmco understands that should it breach any provision of this Agreement, the United States will have the right to use against SB Pharmco before any grand jury, at any trial or hearing, or for sentencing purposes, any statements which may be made by SB Pharmco, and any information, materials, documents or objects which may be provided by it to the government subsequent to this Agreement, without any limitation.

SB Pharmco understands and agrees that this Rule 11(c)(1)(C) plea agreement and its agreed-upon criminal disposition:

- a. are wholly dependant upon SB Pharmco's timely compliance with the material provisions of the attached Civil Settlement Agreement, and that
- b. failure by SB Pharmco to comply fully with the material terms of this Agreement or the attached Civil Settlement Agreement will constitute a breach of this Agreement.

In the event SB Pharmco at any time hereafter breaches any material provision of this Agreement, SB Pharmco understands that (1) the United States will as of the date of that breach be relieved of any obligations it may have in this Agreement and the attached Civil Settlement Agreement, including but not limited to the promise not to further prosecute SB Pharmco as set forth in this Agreement; and (2) SB Pharmco will not be relieved of its obligation to make the payments set forth in this Agreement and the attached Civil Settlement Agreement, nor will it be



entitled to return of any monies already paid. Moreover, in the event of a breach, SB Pharmco understands and agrees that the United States may pursue any and all charges that might otherwise have been brought but for this Agreement, and SB Pharmco hereby waives, and agrees it will not interpose, any defense to any charges brought against it which it might otherwise have under the Constitution for pre-indictment delay, any statute of limitations, or the Speedy Trial Act, except any such defense that SB Pharmco may already have for conduct occurring before April 27, 2002.

15. Who Is Bound By Agreement

With respect to matters set forth in Paragraph 5, this Agreement is binding upon SB Pharmco and the Office of the United States Attorney for the District of Massachusetts, the United States Attorney's Offices for each of the other 93 judicial districts of the United States, and the Office of Consumer Litigation of the Department of Justice. The non-prosecution provisions in Paragraph 5 are also binding on the Criminal Division of the United States Department of Justice, with the exception of any investigations of SB Pharmco that are or may be conducted in the future by the Fraud Section of the Criminal Division regarding possible violations of the Foreign Corrupt Practices Act and related offenses in connection with the sales and marketing of SB Pharmco's products to foreign customers, which investigations are specifically excluded from the release in Paragraph 5. A copy of the letter to United States Attorney Carmen M. Ortiz from the Assistant Attorney General, Criminal Division, Department of Justice, authorizing this Agreement is attached as Exhibit D. SB Pharmco understands that this Agreement does not bind any state or local prosecutive authorities, the Tax Division of the U.S. Department of Justice or the Internal Revenue Service of the U.S. Department of the Treasury.

16. Corporate Authorization

SB Pharmco's acknowledgment of this Agreement and execution of this Agreement on behalf of the corporation is attached as Exhibit E. SB Pharmco shall provide to the U.S. Attorney and the Court a certified copy of a resolution of the governing authority of SB Pharmco affirming that it has authority to enter into the Plea Agreement and has (1) reviewed the Information in this case and the proposed Plea Agreement; (2) consulted with legal counsel in connection with the matter; (3) agreed to enter into the proposed Plea Agreement; (4) agreed to authorize SB Pharmco to plead guilty to the charges specified in the Information; and (5) agreed to authorize the corporate officer identified below to execute the Plea Agreement and all other documents necessary to carry out the provisions of the Plea Agreement. A copy of the resolution is attached as Exhibit F. SB Pharmco agrees that either a duly authorized corporate officer or a duly authorized attorney for SB Pharmco, at the discretion of the Court, shall appear on behalf of SB Pharmco and enter the guilty plea and will also appear for the imposition of sentence.



17. Complete Agreement

This Agreement and the attachments hereto, together with the Civil Settlement Agreement and attachments thereto, and the separate side letter with GlaxoSmithKline LLC and attachments thereto, set forth the complete and only agreement between the parties relating to the disposition of this case. No promises, representations or agreements have been made other than those set forth in this Agreement and its attachments, and the Civil Settlement Agreement and its attachments, and the separate side letter with GlaxoSmithKline LLC and its attachments. This Agreement supersedes prior understandings, if any, of the parties, whether written or oral. This Agreement can be modified or supplemented only in a written memorandum signed by the parties or on the record in court.

If this letter accurately reflects the Agreement between the United States and your client, SB Pharmco, please have the authorized representative of SB Pharmco sign the Acknowledgment of Agreement below. Please also sign below as Witness. Return the original of this letter to Assistant U.S. Attorney Susan G. Winkler.

Very truly yours,



CARMEN M. ORTIZ  
UNITED STATES ATTORNEY  
DISTRICT OF MASSACHUSETTS

By: 

Susan G. Winkler



Shannon T. Kelley  
Assistant U.S. Attorneys  
District of Massachusetts

TONY WEST  
ASSISTANT ATTORNEY GENERAL  
CIVIL DIVISION  
U.S. DEPARTMENT OF JUSTICE

By: 

Mark L. Josephs  
Trial Attorney  
Office of Consumer Litigation  
U.S. Department of Justice



**ACKNOWLEDGMENT OF AGREEMENT**

The Trustee of SB Pharmco Puerto Rico, Inc. (the "Trustee") is authorized to execute this Plea Agreement on behalf of SB Pharmco, Puerto Rico, Inc. and to take all such actions as may be necessary to effectuate this Plea Agreement. The Trustee has read this Plea Agreement, the attached criminal Information, and the Civil Settlement Agreement, including all attachments, in their entirety and has discussed them fully in consultation with SB Pharmco's attorney. The Trustee acknowledges that these documents fully set forth SB Pharmco's agreement with the United States. The Trustee further states that no additional promises or representations have been made to SB Pharmco by any officials of the United States in connection with the disposition of this matter, other than those set forth in the Plea Agreement and the attached Civil Settlement Agreement.

Dated: \_\_\_\_\_

\_\_\_\_\_  
Desmond P. Burke  
Trustee  
SB Pharmco Puerto Rico, Inc.

Dated: \_\_\_\_\_

\_\_\_\_\_  
Geoffrey E. Hobart, Esq.  
Matthew J. O'Connor, Esq.  
Covington & Burling LLP  
Counsel for Defendant